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Behavioural activation for depressive symptoms in adults with severe to profound intellectual disabilities: Modelling and initial feasibility study

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Abstract

Background: Almost no research has been published reporting on evaluations of the effectiveness of psychological interventions for people with severe to profound intellectual disabilities and depression. This paper describes the development and initial feasibility testing of an adapted Behavioural Activation therapy (BeatIt2) for this population.

Method: Phase 1 of the study examined participant recruitment and willingness to be randomised in the context of a planned Randomised Controlled Trial (RCT). Phase 2 examined the feasibility of delivering the intervention.

Results: Twenty adults with a severe or profound intellectual disability and clinically significant depression were recruited to Phase 1 of the study. In Phase 2, there was 100% participant retention for those recruited to the study at 6-month follow-up. The BeatIt2 therapy was reported to be acceptable for participants.

Conclusion: COVID disruption meant that it was not possible to complete the planned feasibility RCT. The positive findings suggest that additional evaluation of BeatIt2 is warranted.

KEYWORDS

behavioural activation, depression, feasibility study, psychological therapy, severe intellectual disability

1 | INTRODUCTION

People with severe and profound intellectual disabilities are at heightened risk of mental ill health, demonstrating a higher prevalence of mental health problems compared both to the general population and to adults with mild to moderate intellectual disabilities (Cooper et al., 2007). Depression is one of the most common mental health problems faced by people with intellectual disabilities and has been

found to be more enduring in people with intellectual disabilities compared with the general population (Collishaw et al., 2004).

Considerable work has been carried out to develop and evaluate the effectiveness of psychosocial interventions for depression in the general population. However, there is an absence of evidence on the use of psychological interventions among people with intellectual disabilities (NICE, 2016; Tapp et al., 2023; Vereenoghe & Langdon, 2013). Recent research has focused on adapting cognitive

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behavioural therapy (CBT) models for use with adults with intellectual disabilities (e.g., Hassiotis et al., 2011), but cognitive based strategies may not be accessible for many individuals with intellectual disabilities, due to the cognitive and communicative demands of the therapy. There is even less evidence for interventions for depression in people with severe to profound intellectual disabilities. Vereenoghe et al.'s (2018) systematic review found no psychological therapy research and only a single case experimental design study of an adult woman with severe intellectual disability and depression receiving pharmacological treatment and environmental enrichment (Lindauer et al., 1999).

There are also complexities in the assessment and diagnosis of mental health problems in people with severe and profound intellectual disabilities that contribute to difficulties accessing appropriate intervention and support, with very few robust measurement tools available (Flynn et al., 2017). Many people with severe and profound intellectual disabilities are unable to report their experiences and symptoms and are reliant on other people to provide proxy reports (Dagnan, 2007). Moreover, emotional problems can present differently in people with severe and profound intellectual disabilities and may be observed through changes in behaviour or sleep patterns, reduced appetite, and/or a loss of interest in activities. This means that without sensitive assessment measures that take account of the individual needs of this population, their mental health problems can often go undetected and untreated (Janowsky & Davis, 2005).

Behavioural activation is a psychological therapy that aims to increase overt behaviours that are likely to bring the individual into contact with positive environmental contingencies, with a corresponding improvement in mood, thoughts, and overall well-being (Lejuez et al., 2011). Behavioural activation can be less reliant than cognitive based strategies on the verbal communication needed to access emotions and cognitions. Therefore, for adults with intellectual disabilities, behavioural activation may be more accessible in the management of depression. A detailed account of the adaptation of behavioural activation for people with more severe and profound intellectual disabilities and depression, and the theoretical underpinnings of the approach, are provided in a linked paper (Jahoda et al., *in press*). Jahoda et al. (2017) conducted a randomised controlled trial (RCT) of an adapted behavioural activation intervention for depression (BeatIt) in adults with mild to moderate intellectual disabilities. Participants were allocated to receive either the BeatIt intervention or an adapted guided self-help intervention (StepUp). Jahoda et al. reported that participants in both intervention groups showed a marked improvement in mood by 4 months post-randomisation, with improvements in depression symptoms sustained at 12 months post-randomisation.

In the current study, we adapted the BeatIt intervention for adults with severe and profound intellectual disabilities and depression (BeatIt2). A detailed account of the adaptations is reported in (Jahoda et al., *in press*). In the current paper, we report on a feasibility study of this modified intervention. The primary aim was to assess the feasibility of a future large-scale RCT of the BeatIt2 intervention. We

included health economics work in this feasibility study in line with best practice (Skivington et al., 2021). Results from this work are valuable for informing an economic evaluation if the intervention goes to a full definitive trial.

Data were collected to address the following research questions: (i) what is the rate of recruitment of adults with depression and severe intellectual disabilities to the study; (ii) what is the retention rate of participants at 6 months follow-up; (iii) what is the feasibility of collecting service use and outcome data for an RCT; (iv) is the BeatIt2 intervention delivered with fidelity to the manual/model and what is the adherence of participants to the treatment; (v) are there adverse events associated with the BeatIt2 intervention; (vi) which outcome measures have utility in detecting change in participants with severe intellectual disabilities and their carers; (vii) what is the cost of delivering BeatIt2 to adults with severe intellectual disabilities; and (viii) how acceptable is the modified BeatIt2 intervention for adults with severe intellectual disabilities, their carers, and therapists.

2 | METHOD

2.1 | Design

The BeatIt2 study was planned as a two-centre feasibility RCT of BeatIt2 compared to treatment as usual (TAU). Participants were to be randomised to receive the behavioural activation intervention, or to receive TAU. After initial recruitment, in keeping with regulations affecting all research in the UK involving close contact between clinicians/researchers and study participants, the study had to be paused between March and December 2020, in response to the COVID-19 pandemic. Hence, it was not possible to complete the RCT and there were two distinct phases to the research.

During Phase 1, prior to the pandemic, data were obtained about participant recruitment for a feasibility RCT and willingness to be randomised. For Phase 2, as our feasibility question on willingness to be randomised to a RCT study had already been addressed, a pre-post evaluation design was used where all participants received the intervention. There was also an ethical dimension to this decision by the research team, given the significant impact of the pandemic on the mental health of people with intellectual disabilities and their limited access to specialist help at the time. During Phase 2, data were obtained on the feasibility of delivering the BeatIt2 intervention and outcome measures were collected at baseline prior to starting the intervention, and at 6-months post-baseline. Semi-structured interviews were also carried out with a selected sample of supporters and therapists to capture their experiences and perspectives of the BeatIt2 treatment.

2.2 | Participants

Participants were recruited from sites in the West of Scotland and North West England. Inclusion criteria for participation in this study

were: a severe to profound intellectual disability, defined administratively and confirmed by carer report using the Vineland Adaptive Behaviour Scales, with an ABC composite score of 50 or below (Sparrow et al., 2016). The participants in our study had high support needs, limited or no expressive or receptive verbal communication, and significant impairments across adaptive functioning skills. Participants were also required to have clinically significant depressive symptoms as confirmed by carers using the Diagnostic Criteria for Psychiatric Disorders for use with Adults with Learning Disabilities (DC-LD; Cooper et al., 2003). The DC-LD uses operationalised diagnostic criteria specifically designed for use with adults with moderate to profound intellectual disabilities. It uses a hierarchical approach to identify the severity and causes of the person's intellectual disability and the presence of additional psychiatric disorders. Four or more symptoms are required to be present and symptoms should have been present on most days for at least 2 weeks. As the participants in our sample were unable to self-report, it was important to identify a carer that knew the person well to complete this measure. Participants were required to be 18 years of age and over; and have a family member or paid carer (supporter) who had supported the individual for a minimum of 6 months and was able to complete the research measures and available to attend therapy sessions.

Socio-demographic characteristics of recruited participants from both study phases are presented in Table 1. For participants who received the intervention, we also collected data about their supporters, who were mainly support workers and family carers.

For the qualitative component of this research at Phase 2, five individuals (4 women, 1 man) who supported a participant with the BeatIt2 intervention were interviewed (2 paid carers, 1 intellectual disability nurse, and 2 mothers). Three therapists who had delivered the BeatIt2 intervention also participated in an interview.

Four therapists in each study site delivered the BeatIt2 intervention. The job roles of the BeatIt2 therapists were: clinical psychologist ($n = 3$), assistant psychologist ($n = 2$) and learning disability nurse ($n = 3$). All therapists had previous experience of working with people with intellectual disabilities. The therapists attended a one-day training course and received fortnightly supervision from a consultant clinical psychologist at each site.

2.3 | Measures

All outcome measures described below were completed by a family member or paid carer of the person with intellectual disabilities who had known them for a minimum of 6 months. Members of the research team

TABLE 1 Socio-demographics of the recruited participants and participants in the beatIt2 therapy intervention who were followed up in Phase 2 ($n = 15$).

	Phase 1: Participants recruited and eligible (<i>n</i> = 20)	Phase 2: Participants recruited and eligible (<i>n</i> = 17)	Participants in the intervention who were followed up in phase 2 (<i>n</i> = 15)	Supporters of participants in the intervention who were followed up in phase 2 (<i>n</i> = 15)	
Sex				Sex	
Male	7	11	10	Male	4
Female	13	6	5	Female	11
Age				Age	
Mean (SD)	39.8 (14.27)	40.06 (11.61)	38.87 (11.87)	Mean (SD)	48.36 (11.76)
Range	21–57	21–59	21–59	Range	23–63
Ethnicity				Ethnicity	
White British	19	16	14	White British	14
Asian/Asian British	1	1	1	Asian/Asian British	1
Usual place of residence				Relationship to participant	
Family home	9	6	5	Parent	4
Supported living (staffed individual/group living)	11	9	8	Support worker	7
NHS sector hospital	0	2	2	Manager of day service	1
				Practitioner	3

were funded to carry out a systematic review of mental health measures for people with intellectual disabilities (Flynn et al., 2017). Evidence from this review informed the selection of the highest quality and most appropriate measures for use in the current study.

2.3.1 | Planned primary outcome for a large-scale effectiveness study

Intellectual disabilities depression scale

This is a 38-item behavioural checklist derived from DSM-III-R criteria, designed to measure the frequency of identified depressive behaviours within a four-week period. Higher scores indicate a higher frequency of depressive symptoms. The intellectual disabilities depression scale (IDDS; Evans et al., 1999) shows acceptable levels of inter-rater agreement (82%) when completed by carers for adults with severe/profound intellectual disabilities (Evans et al., 1999).

2.3.2 | Planned secondary outcomes for a large-scale effectiveness study

The mood interest and pleasure questionnaire—short form

The MIPQ comprises 12 items from two subscales (mood, and interest and pleasure) and requires proxy respondents to indicate how often a particular symptom has occurred within the last 2 weeks. Lower scores indicate lower mood and lower levels of interest and pleasure. The mood interest and pleasure questionnaire (MIPQ; Ross et al., 2008; Ross & Oliver, 2003) short form shows high internal consistency (Cronbach alpha coefficients: total = .88; mood = .79; interest and pleasure = .87) (Ross et al., 2008).

Anxiety, depression and mood scale

Seven items were used from the original 28-item measure (anxiety, depression and mood scale—ADAMS; Esbensen et al., 2003). These items comprise the 'generalised anxiety' subscale, with informants reporting on their observations of these symptoms in the last 2 weeks. Items are scored on a four-point Likert scale that combines frequency and severity of symptoms. The other sub-scales were not administered as data on depressive symptoms and low mood were collected via other measures. The generalised anxiety subscale demonstrated good internal consistency (Cronbach's alpha = .83) among carers of people with intellectual disabilities (Esbensen et al., 2003).

Vineland adaptive behaviour scale 3

This is a standardised assessment measure of adaptive functioning. The domain version was used in the present study. It uses a semi-structured interview methodology, with informants reporting across three broad domains: communication, daily living skills and socialisation. Nine items were used from the maladaptive domain of the Vineland adaptive behaviour scale 3 (VABS). Higher scores indicate a higher frequency of maladaptive behaviours. The VABS demonstrated

good internal reliability (Cronbach's alpha ranging from .85 to .91) (Sparrow et al., 2016).

Index of community involvement

This 16-item scale provides a measure of participation in social and community-based activities during the previous 4 weeks. Higher scores indicate a higher frequency of engagement. The (index of community involvement) ICI has demonstrated good internal consistency (Cronbach's alpha = .79; Raynes et al., 1989).

Index of participation in domestic life (IPDL)

This scale measures participation in 13 household tasks during the previous 4 weeks. Higher scores indicate higher levels of independent participation in domestic tasks. This scale has been reported to have good internal consistency (Cronbach's alpha = .89; Raynes et al., 1989).

EQ-5D-Y

This scale measures health related quality of life across five dimensions (mobility, looking after self, doing usual activities, having pain or discomfort, feeling worried, sad, or unhappy) using a three-point Likert scale (1: no problems, 2: some problems, 3: a lot of problems) (Wille et al., 2010). Respondents also record the person's overall health on a visual analogue scale, where 0 indicates 'the worst health you can imagine' and 100 indicates 'the best health you can imagine'. This measure showed good test re-test reliability (86.2%–99.7%) across dimensions (Ravens-Sieberger et al., 2010).

Emotional difficulties self-efficacy scale (EDSE)

A 10-item scale was developed for the present study to measure carers' confidence in supporting the person with intellectual disabilities when they are feeling down. This was an adaptation of a measure used in previous research (Jahoda et al., 2017). In line with the core elements of behavioural activation, additional items were developed to measure carer confidence in supporting the person with intellectual disabilities to engage in activity when they are feeling down. This included the carer's confidence about supporting the person to establish a daily routine, to identify activities in their local area, and plan activities to do in the coming days. Two further items were developed to measure carers' confidence in seeking help, if they were finding it difficult to support the person with intellectual disabilities. All items are scored on a 9-point Likert scale, where 0 indicates 'not at all confident' and 8 indicates 'extremely confident'. Higher scores indicate a higher level of self-confidence in supporting someone. This measure showed strong internal reliability (Cronbach's alpha = .89).

Client service receipt inventory

The client service receipt inventory (CSRI) is a validated tool to measure total resource use and has been used in evaluations involving people with intellectual disabilities (Chisholm et al., 2000). This provides a measure of the participant's receipt of hospital-based services (inpatient and outpatient attendances), receipt of community-based services (contact with community-based primary care, other health or social services and educational services), and use of medication.

Interview topic guide

Individual supporter and therapist topic guides were developed with open-ended questions as prompts for areas to be discussed. The guides included questions designed to capture supporters' and therapists' perspectives on the process of change, helpful and unhelpful aspects of the intervention, characteristics of the therapeutic relationship, and barriers to the person's participation in the therapy.

Development and content of the adapted behavioural activation manualised therapy

The BeatIt intervention was adapted for people with severe and profound intellectual disabilities in the initial phase of this research, leading to the development of the BeatIt2 manual. This process is detailed in (Jahoda et al, [in press](#)). In brief, BeatIt2 consists of 12 therapy sessions, with an additional session before therapy starts to collect background data from key family members and support workers and to inform them about the nature of the intervention and the role of the supporter in therapy sessions. The person with an intellectual disability engages in joint activities with their supporter at each of the sessions. An initial assessment and socialisation phase (5 sessions) ends with a shared formulation and plan for joint work (implemented in the following 5 sessions). The final two sessions mark the end of therapy and the presentation of an updated version of the formulation booklet. The final booklet details the work carried out in the sessions and highlights ways of maintaining or building on any progress that has been made. Activity scheduling and tackling barriers to change are core elements of the therapy. A detailed description of the formulation process is described in a linked paper concerning the adaptation of the intervention (Jahoda et al., [in press](#)).

2.4 | Procedure

Ethical approval for this study was granted from The Scotland A REC committee (18/SS/0128) and the Wales REC 4 Committee (19/WA/0073). In keeping with the Adults with Incapacity Act (Scottish Executive, 2000) and the Mental Capacity Act (UK Government, 2005), consent was obtained from the person's relative, welfare guardian or welfare attorney in Scotland, or the personal or nominated consultee in England. Participants were recruited through specialist intellectual disability health services, third-sector organisations, residential care, and day services for adults with intellectual disabilities. Carers completed a screening assessment with a researcher to confirm that the person with intellectual disabilities met eligibility criteria to participate.

In Phase 1, consent and data collection took place face-to-face. In Phase 2, consent and outcome data were collected remotely by telephone or video call. Participants from Phase 1 who provided consent and baseline data but did not start or complete the intervention, were contacted and invited to take part in Phase 2 of the study. Participants were re-consented and baseline data were collected again. For these participants, the most recent baseline data collected are reported in this paper.

Semi-structured interviews with supporters and therapists were primarily completed remotely by video call ($n = 6$) or telephone

($n = 1$), with one interview with a therapist being completed face-to-face. Interviews were audio-recorded. The average duration of the interviews was 65 min for supporters (Range: 24.6–120.9 min) and 51 min for therapists (Range: 43.2–60.2 min).

2.5 | Analyses

Rate of participant recruitment and retention were reported as counts by study phase. Adherence to the therapy was defined as attendance at a minimum of eight BeatIt2 sessions. Eight sessions, including a minimum of three intervention sessions and a formulation session, was considered sufficient to have received the key elements of the intervention. Sessions were completed sequentially, and participants could not proceed to the next session until the previous session had been completed. The number of adverse events was reported. Summary statistics were presented on participant scores on each study outcome measure, at baseline and follow-up. Data completeness for each measure was also reported. This feasibility study is not powered to explore efficacy. The outcome data will be used to estimate the standard deviation of the data for the different outcomes and will be used to inform sample size calculations for the next phase of this study. Mean change scores and associated 95% confidence intervals and effect sizes were reported for each outcome measure to assess sensitivity to change. Therapist adherence to the manual was assessed using an adapted version of the fidelity instrument developed for the recent large scale BeatIt RCT (Jahoda et al., 2017). The therapists indicated whether they adhered to the different session elements on a dichotomous yes/no scale. The mean number of session elements was reported for the intervention as a whole and for each individual session. Information on resource use in the last 4 months was collected. The financial costs were summed and divided by the number of participants to give a mean cost per participant. Further information on the calculation of these costs is reported in Data S1.

Framework analysis was used to examine supporters' and therapists' views of the modified BeatIt2 intervention. Framework analysis is a structured method of qualitative analysis which allows researchers to begin with a set of a priori themes which are used as an initial guide to the analysis (Ritchie & Spencer, 1994). The interviews were transcribed verbatim. An initial coding framework was developed by the research team which closely aligned with the interview topic guide as this was informed by the feasibility questions for the study. Two of the authors reviewed and coded each interview transcript independently and reached agreement on the final coding framework.

3 | RESULTS

3.1 | Phase 1: Recruitment and randomisation to the RCT (prior to study suspension due to COVID-19)

Figure 1a shows that in Phase 1, 30 participants were interested in taking part in the study (consent was obtained). Twenty of the participants (6 men, 14 women) met the eligibility criteria and were recruited

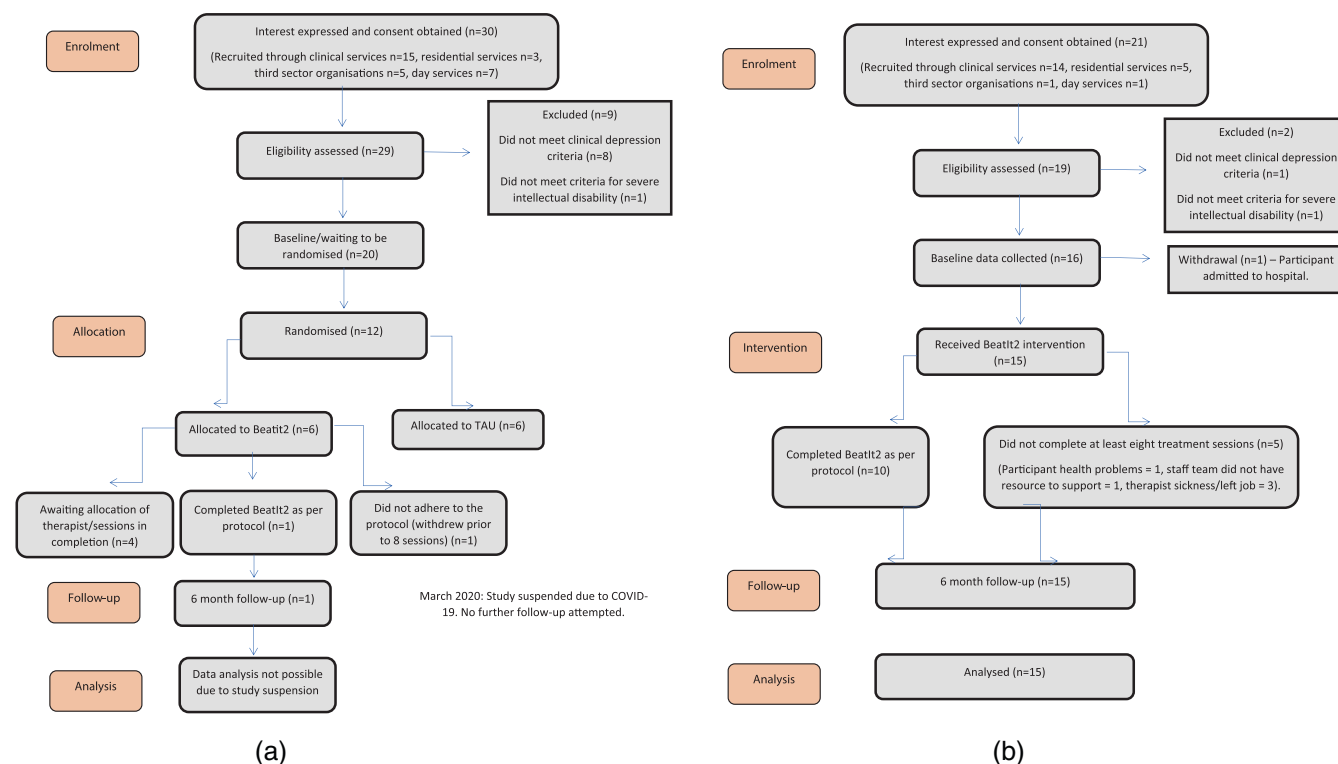


FIGURE 1 (a) Recruitment and retention consort diagram: Phase 1 (recruitment period: May 21, 2019–February 29, 2020). (b) Recruitment and retention consort diagram: Phase 2 (recruitment period: February 26, 2021–October 27, 2021).

over a 7-month period. Eight participants did not meet criteria for clinical depression and one participant did not meet criteria for a severe or profound intellectual disability. One participant was awaiting eligibility assessment at the time the study was paused. At the point of study suspension, 12 participants had been randomised, and eight participants were awaiting baseline/randomisation. Two participants had fully or partially completed the intervention.

Recruitment involved between one and three meetings with each service. The researchers also held an information session for family carers. Detailed recruitment records were kept at the Scottish study site. Due to administrative problems, we are not able to report this information with reliability for the second site. At the Scottish site, the researchers disseminated a total of 87 study information packs. Packs were distributed by seven NHS intellectual disability teams, 2 day-services, and two charitable organisations. The staff members were supposed to hand out the packs to potential participants they had identified. However, it should be noted that we did not receive confirmation that all packs were received by the potential participants. This translated to the recruitment of 14 participants at the Scottish site.

3.2 | Phase 2 post-study suspension for COVID-19

3.2.1 | Recruitment of participants

Figure 1b shows that 21 participants were interested in taking part in the study (consent was obtained). Nineteen participants were screened for

eligibility and 17 (10 men, 7 women) met the eligibility criteria and were recruited to phase 2 of the BeatIt2 intervention. One participant did not meet eligibility criteria for clinically significant depression and one participant did not meet eligibility criteria for a severe intellectual disability.

3.2.2 | Retention at 6 months follow-up

Follow-up data were collected for 15 of the participants recruited in Phase 2. The average time for follow-up was 26.2 weeks. Follow-up data were collected for nine of the participants within the planned 20–28 weeks window. Data collection was extended for the remaining six participants, due to sickness, carers being required to self-isolate, and staff shortages in social care settings.

3.2.3 | Adherence to the intervention

One participant was withdrawn from the study prior to the intervention starting because they were admitted to hospital. Ten of the remaining 15 participants completed the intervention as per protocol (a minimum of eight sessions), with nine of these participants completing all 12 sessions. Five participants failed to complete the intervention as per protocol. This was due to participant health problems, therapist sickness or change of jobs, and staff teams not having the capacity to support the study. Participants completed an average of 9.4 (SD: 4.2) consecutive sessions.

3.2.4 | Fidelity to the manual

Therapists were asked to provide fidelity ratings for all therapy sessions, and ratings were available for 75% of completed sessions. In terms of fidelity to the manual, therapists reported conforming to an average of 92.8% of the session elements. Table 2 shows the number of elements conformed to per session. Therapists also rated themselves highly on all dimensions of therapy quality, with a mean score of 3.8 or above (out of 5) for all specified dimensions (engagement, hopefulness, rapport, and acceptance).

3.2.5 | The utility of outcome measures in detecting change in the participants with severe intellectual disabilities, and their carers

Table 3 shows pre and post-intervention scores across the outcome measures for the sample of 15 participants who provided follow-up data in Phase 2. There was a reduction in participants' depressive symptoms on the IDDS (Mean change = -16.27 (SD = 28.26); 95% CI 0.62, 31.92; $d = .58$) and a reduction in anxiety symptoms on the ADAMS (Mean change = -3.47 (SD = 6.85); 95% CI -3.33 , 7.26; $d = .51$) from pre-intervention to 6 month follow-up. Changes to individual scores for the primary outcome measure IDDS are shown in Figure 2. There was an increase in participants' engagement in community activities from pre-intervention to 6 month follow-up (Mean change = 2.40 (SD = 7.22); 95% CI -6.40 , -1.60 ; $d = .33$). There was little change between pre-intervention and 6 month follow-up for all other secondary outcomes.

4 | PHASES 1 AND 2

4.1 | Data completeness

Table 4 reports on data completeness for the outcome measures. Four participants did not complete the VABS maladaptive behaviour scale at baseline due to an error in researcher administration and the EDSE was not completed by one participant at follow-up. Across all other outcome measures, the proportion of missing data was <5%. It was not possible to compute a total score for one participant on the EQ-5D-Y due to incomplete data. For all other participants, data completeness was sufficient to allow a total score to be computed.

4.2 | The cost of delivering BeatIt2 to adults with severe intellectual disabilities

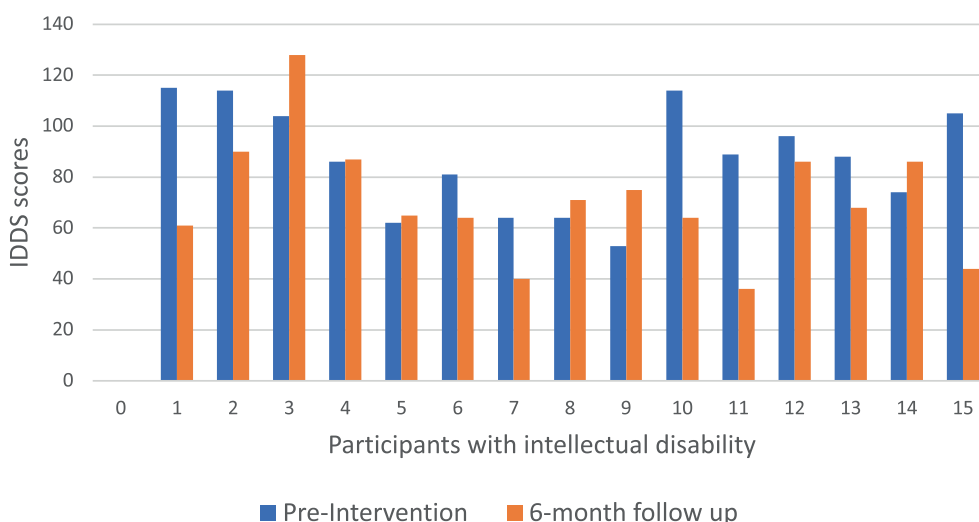
Costs were calculated for all participants recruited into the intervention for whom service use data was collected. As shown in Table 5, missing data for the different sub-sections of the CSRI at baseline ranged from one to nine participants partially complete, and two to three participants missing all data. Nine participants were not followed up from Phase 1 as the study was paused due to the COVID-19 pandemic and two to six participants had partially complete data from one of the sub-sections at follow-up. Mean costs at baseline for healthcare, community services and accommodation were

TABLE 2 Therapists' fidelity to the BeatIt2 manual.

	Supporter session (n = 13)	Session 1 (n = 11)	Session 2 (n = 11)	Session 3 (n = 11)	Session 4 (n = 11)	Session 5 (n = 10)	Session 6 (n = 9)	Session 7 (n = 9)	Session 8 (n = 9)	Session 9 (n = 9)	Session 10 (n = 8)	Session 11 (n = 7)	Session 12 (n = 7)
Possible session elements	10	7	9	9	9	12	10	10	10	10	10	11	9
Mean (SD) session elements completed	9.85 (0.4)	6.67 (1.0)	8.90 (2.13)	8.56 (1.01)	8.11 (1.36)	11.3 (1.13)	9.78 (1.39)	9.0 (1.20)	9.13 (1.36)	9.13 (1.13)	9.14 (1.46)	9.5 (1.76)	7.71 (2.36)
Range	9–10	4–7	5–12	6–9	5–9	9–12	7–10	7–10	6–10	7–10	6–10	7–11	3–9

TABLE 3 Pre and post-intervention scores on outcome measures in Phase 2 ($n = 15$).

Scale (minimum, maximum)	Pre-intervention	6 month follow-up	Mean change (SD)	95% CI
Intellectual disability depression scale (IDDS) (0, 228)	$N = 15$ Mean: 87.27 (SD: 20.68) Range: 53–115	$N = 15$ Mean: 71.0 (SD: 23.12) Range: 36–128.	–16.27 (28.26)	0.62, 31.92
The mood interest and pleasure questionnaire (MIPQ)				
Mood (0, 24)	$N = 15$ Mean: 15.47 (SD: 3.80) Range: 8–21.	$N = 15$ Mean: 16.0 (SD: 4.24). Range: 7–21.	.53 (5.13)	–3.37, 2.30
Interest and Pleasure (0, 24)	$N = 15$ Mean: 11.53 (SD: 3.87) Range: 7–22	$N = 15$ Mean: 13.53 (SD: 5.89) Range: 0–22	2.0 (5.21)	–4.89, 0.89
Anxiety Depression and Mood Scale (ADAMS)—total (0, 42)	$N = 15$ Mean: 18.27 (SD: 7.14). Range: 5–30.	$N = 15$ Mean: 14.8 (SD: 5.82). Range: 2–23.	–3.47 (6.85)	–.33, 7.26
VABS Maladaptive scale (0, 18)	$N = 12$ Mean: 5.58 (SD: 2.46). Range: 2–10.	$N = 12$ Mean: 4.17 (SD: 2.08). Range: 1–7.	–1.42 (2.50)	–.17, 3.01
Index of community involvement (0, 80)	$N = 15$ Mean: 13.8 (SD: 7.38). Range: 0–27.	$N = 15$ Mean: 16.2 (SD: 7.73). Range: 1–29.	2.40 (7.22)	–6.40, 1.60
Index of domestic participation (0, 26)	$N = 15$ Mean: 5.67 (SD: 4.95). Range: 0–16.	$N = 15$ Mean: 6.20 (SD: 5.55). Range: 0–17.	–.53 (4.72)	–3.15, 2.08
Emotional difficulties self-efficacy scale (0, 80)	$N = 14$ Mean: 57.5 (SD: 12.91). Range: 32–76.	$N = 14$ Mean: 60.93 (SD: 10.97). Range: 37–80.	3.43 (13.90)	–11.46, 4.60
EQ-5D-Y: Health utility score	$N = 14$ Mean: 0.17 (SD: .35). Range: –.50–0.88	$N = 14$ Mean: 0.25 (SD: .42). Range: –.50–.85	.08 (.38)	–.30, 1.40

**FIGURE 2** Participant with intellectual disabilities' IDDS scores pre-intervention and at 6-month follow-up.

£35,410 per participant, the largest component of this cost was accommodation (82%). Therapist costs for the intervention were £821 per participant, materials £57, and total of £878 per participant. Health utilities from the EQ-5D-Y were a mean score of 0.234 at baseline and 0.225 at follow-up; the mean VAS score was 56.08 and 54.38 at baseline and follow-up.

4.3 | Adverse events

No serious related adverse events were reported for any of the participants recruited to either Phase of the study (the hospitalisation of one person was not associated with participation in the study).

5 | ACCEPTABILITY OF THE ADAPTED BeatIt2 INTERVENTION, AND FACILITATORS AND BARRIERS

5.1 | Acceptability

5.1.1 | Interviews with supporters

The supporters spoke positively about the BeatIt2 intervention as an acceptable therapy for the person with intellectual disabilities. The participants with intellectual disabilities were reported to engage well with the intervention activities:

TABLE 4 Data completeness across outcome measures (depressive and anxiety symptoms, activity levels, challenging behaviour, quality of life, carer self-efficacy).

Outcome measure	% missing (N participants with any missing data) ^a	% missing (N participants with any missing data)
	Baseline (n = 25)	6 month follow-up (n = 16)
Intellectual disability depression scale	2% (n = 8)	2% (n = 6)
The mood interest and pleasure questionnaire	No missing data	1% (n = 2)
Anxiety depression and mood scale	1% (n = 1)	No missing data
Vineland adaptive behaviour—maladaptive scale	Measure not completed due to administering error (n = 4)	2% (n = 2)
Index of community involvement	No missing data	No missing data
Index of domestic participation	No missing data	No missing data
EQ5D-Y	1% (n = 1)	No missing data
Emotional difficulties self-efficacy scale	No missing data	Measure not completed (n = 1)

^aMissing data are defined as a respondent leaving blank an item on a measure. Missing data for each outcome is reported as a percentage of the total sample responses for that outcome measure. Where a participant did not provide any data on a measure, this is noted.

He really quickly took to getting involved in the activities that we had set up... he was making a cup of tea for (therapist) and things like that that we had used as purpose skills that we were building, but he was more than happy to.

A key element highlighted by supporters was the person with intellectual disabilities' acceptance of the therapist. Supporters also reported that they got on well with the therapist and described working in partnership and learning together through the intervention:

So, we will realise something together and will say we can try this and maybe this. Yeah, it's been lovely to work with (therapist).

This partnership working appeared to contribute to a sense of shared achievement.

Supporters also highlighted positive changes for the person with intellectual disabilities through taking part in the BeatIt2 therapy

including: improved mood, increased confidence, reduction in challenging behaviours, improved sleep, more enjoyment of activities, skill development, increased independence, and the ability to make choices. They highlighted that small meaningful changes had the potential to make a real difference to the person's life. For example, being able to choose a drink or a snack, or playing a small role in making a cup of tea:

What I probably have learned in the last 2 or 3 years is small things, small things are massive, small things are huge in the context of (person with intellectual disability) life. Something small but something we can use on a daily basis could actually end up having a profound effect on his day.

Supporters talked about benefiting from participating in the BeatIt2 intervention. They reported that they had become more aware of the value of purposeful activity and ideas about how to engage the person they supported in activity. Some supporters felt that the intervention had helped to boost their own sense of self-efficacy as a carer, reducing the pressure they felt to always get it 'right'.

It sort of reinforced that we are heading in the right direction, we are doing everything that we can do, that it's not a matter of missing stuff, it's not that we are not doing it right, it's just that sometimes it doesn't work for (person with intellectual disability) and that's all there is to it. More acceptance there I suppose.

5.1.2 | Interview with therapists

The therapists were positive about their experience of delivering the intervention and felt that the learning had helped to inform their practice. They also reported that the participants with intellectual disabilities engaged well in the therapy activities and showed enjoyment during the sessions:

So I had just taken along some herbs, some mint, some rosemary... things that he could touch, smell, and make noise with...I think from the first session what really took my breath away was actually the length of time he was able to sustain that...he was engaging, he was partaking, he was smiling, you know it was really great.

The therapists observed changes across sessions, for example gaining independence in choosing a drink:

It was lovely to see because he chose very quickly, he liked particular colours of cups, styles of cups, he knew where the things all were, and it was lovely just to see him be encouraged to increase his independence.

TABLE 5 The cost of delivering BeatIt2 to adults with severe intellectual disabilities (Resource use in the last 4 months).

Missing data for resource use			
	Baseline		
	Complete	Partially complete	Missing all
Daytime activities	17 (68%)	8 (32%)	0
Hospital-based	25 (100%)	0	0
Medication	25 (100%)	0	0
Community-based activities	16 (64%)	9 (36%)	0
Staff/unstaffed supported living	15 (60%)	8 (32%)	2 (8%)
Informal care at home	15 (60%)	7 (28%)	3 (12%)
EQ-5D-Y	24 (96%)	1 (4%)	0
	Follow-up		
	Complete	Partially complete	Missing all
Daytime activities	14 (56%)	2 (8%)	9 (36%)
Hospital-based	16 (64%)	0	9 (36%)
Medication	16 (64%)	0	9 (36%)
Community-based activities	10 (40%)	6 (24%)	9 (36%)
Staff/unstaffed supported living	11 (44%)	5 (20%)	9 (36%)
Informal care at home	11 (44%)	5 (20%)	9 (36%)
EQ-5D-Y	16 (64%)	0	9 (36%)
Therapist	17 (68%)	0	8 (32%)
Baseline health and social care costs			
	Mean cost per participant (SD)		
Resources used by population			
Daytime activities	£2992 (£5752)		
Hospital-based	£2956 (£9169)		
Community-based activities	£431 (£567)		
Staff/unstaffed supported living/informal care at home	£29,031 (£9442)		
Total costs	£35,410 (£11,095)		
Intervention cost			
Therapist preparation	£216 (£295)		
Therapist sessions	£376 (£217)		
Therapist travel	£229 (£261)		
Materials	£57 (£0)		
Total	£878 (£635)		
EQ-5D-Y			
	Baseline (Mean SD)	Follow-up (Mean SD)	
Health utility	0.234 (0.322)	0.225 (0.398)	
VAS	56.08 (27.79)	54.38 (20.97)	

5.2 | Facilitative factors

5.2.1 | Interview with supporters

The fact that the therapists spent time with the person with intellectual disabilities and worked with them directly was contrasted with the consultancy role adopted by other visiting professionals and was viewed as a key element of therapy. Having the flexibility to

accompany the person to different settings was also thought to provide insight into the person's life. One mother reported:

I think that was really, really a massive part of how we managed to make so much progress because there was so many different layers to take into consideration and (therapist) got a good picture of that, how (person with intellectual disability) life runs.

Supporters felt that time was also needed to gain an accurate picture of the person's mood and presentation, given the fluctuating nature of individuals' moods:

You see several different changes of mood in (person with intellectual disability) within the course of that day, that's the reality... and that's why I think over a 12-week period is just about right as you're not going to get too much information if it's only a week or two.

The formulation booklet was thought to be a helpful reminder of the progress they had made:

It was a good sort of refreshing reminder of how far we've come as I think sometimes when you are just trying to push through and get to the next day or try and help (person with intellectual disability) cope, you forget how hard it was when it starts to get easier. So it's good for reflecting on to see that there's always progress there.

5.2.2 | Interview with therapists

The supporter was thought to play a key role in the success of the intervention. They helped the therapist to understand how the person communicates and the nature of their emotional and behavioural reactions. However, they also thought that spending time with the person with intellectual disabilities was crucial in allowing them to develop an understanding of the person. Engaging directly in activities with the person with intellectual disabilities was believed to be particularly beneficial when working with individuals with more limited communication skills:

It can be difficult as he has got no verbal communication so actually doing an activity, you are able to have some quality time with him....if I sat with a pen and paper, I don't know, he might not have engaged for 45 minutes but finding something that I knew that he could relate to and that he enjoyed he was then able to sniff, eat, lick, rub against his face. We put lentils in a box, and he could shake them, and he loved making noise.

Therapists reported that the heterogeneous nature of participants with severe to profound intellectual disabilities meant that there were marked differences in terms of their ability to participate in therapeutic tasks, like completing mood diaries:

I think probably as a therapist it's knowing the material and knowing you need to be adaptable...because everybody doesn't fit into certain boxes so it's probably about having a real think about tweaking it just to

make sure everybody is given the opportunity, if they are able to do it, then absolutely they should be involved in doing it.

As most participants were unable to verbally express their feelings, they highlighted the need to be sensitive to fluctuations in the person's mood and to adapt activities or stop sessions where needed:

Sometimes it didn't happen, just depending on the patient's mood and not to be despondent about that because his mood could be very different from the start of the activity to the end of the activity so I think we had to just be very flexible as well with the patient sometimes and seize that wee (small) opportunity when we could.

5.3 | Barriers

5.3.1 | Interview with supporters

Supporters talked about the need for the participants' wider support team to understand BeatIt2 for therapy tasks to be completed between sessions and changes to be sustained post-intervention. However, some supporters reported practical challenges in sharing knowledge within the team, with different shift patterns reducing the opportunities to communicate with colleagues:

Unfortunately, as much as I'd had conversations with them both and put messages in the communication book to speak about the importance of like filling in the diaries, the activity diaries and that was quite hit and miss...I just think it's something that you want everyone singing from the same hymn sheet on.

It was felt that the material could have been more engaging, to allow those who could, to take part in the therapy tasks. As one supporter said of the mood diaries:

He really enjoys visual and the mood diary was very written...so for us it was just creating a photo wall of his activities rather than written piece because it was something that he could put in rather than we're putting it in.

5.3.2 | Interview with therapists

While obtaining the perspectives of the person's wider support team was seen as beneficial, there were practical challenges in arranging meetings with support teams. Moreover, in supported accommodation, shift patterns could lead to a lack of consistent support. This meant that it was necessary to recap on the purpose of BeatIt2 with

different team members and not all workers were found to have the same investment in supporting the intervention:

Some of the supporters have been harder to work with than others and less willing to try new things. It's been a little bit difficult on some occasions and I think some people have struggled with it as some people are adamant that they know what the client likes, how the client likes it, so they are unwilling to try new things or do different things.

6 | DISCUSSION

It proved possible to recruit adults with severe to profound intellectual disabilities to a RCT of adapted behavioural activation for treatment of depression, and participants were willing to be randomised (Phase 1 of the study). We were also able to recruit participants to Phase 2 of the study, a pre-post evaluation of the BeatIt2 therapy, despite some COVID-19 restrictions remaining in place. Moreover, while therapists emphasised the need for flexibility in the delivery of the BeatIt2 intervention with participants who have severe and profound intellectual disabilities, they reported good fidelity to the manual. This suggests that it is possible for therapists to deliver an adapted version of behavioural activation therapy that is consistent with core aspects of the therapeutic model (Lejuez et al., 2011). While therapists and supporters viewed the intervention as both acceptable and appropriate for people with more severe to profound intellectual disabilities, they highlighted the heterogenous nature of this population and the need to individualise the approach within the framework provided by the manual. In particular, they emphasised the need to set realistic goals and thought that small changes could have a significant impact on individuals' lives.

The successful recruitment of participants to a study for people with more severe to profound intellectual disabilities and depression is notable, given the challenges of diagnosing depression in this population (Janowsky & Davis, 2005). The recruitment strategy asked potential referrers to identify those they thought showed behavioural signs of a significant depression, usually as a component of a more complex presentation. It was made clear the research team would then screen individuals for suitability to participate in the study. The successful recruitment and willingness of the carers of these individuals for their loved ones to be randomised or otherwise recruited into a pre-post intervention study might also reflect the limited access they have to specialist support for mental health problems and their willingness to pursue any available avenues.

There was excellent participant retention at 6-month follow-up. As we were collecting data remotely, we were able to offer flexibility in scheduling appointments and arranged research assessments at convenient times for participants. The continuity of researchers between baseline and follow-up assessment also helped to build positive rapport between participants and researchers. These factors may have contributed to our strong rates of participant retention.

The putative primary outcome measure, the IDDS (Evans et al., 1999), appeared to be sensitive to change with a reduction in depressive symptoms from baseline to 6-month follow-up in Phase 2 of the study. There was also evidence of change in the scores on some secondary outcomes, including a reduction in participants' anxiety symptoms and an increase in engagement in community activities from baseline to 6-month follow-up. However, careful thought needs to be given to the measurement of change in activity, as the measures were not sensitive to small changes that supporters viewed as being salient. For example, the measure of domestic participation that was used (Raynes et al., 1989) did not include minor domestic tasks such as helping with household recycling. Given the focus on increasing engagement in activity in behavioural activation activities, this is a key area of measurement, particularly if a future study aims to examine mechanisms of change. The use of bespoke measures may be helpful in this regard.

While the therapists' checklists suggested that the BeatIt intervention was delivered with good fidelity, in terms of adherence 10 of the 15 participants (67%) completed the intervention per protocol. Among participants who did not complete the intervention as per protocol, this was not due to participant factors but issues relating to the therapists (such as therapist sickness and change of jobs) and, in one instance, the residential service being unable to support the delivery of the intervention. When considering this finding, it is important to reflect on the fact that the intervention phase of the study occurred during the second year of the COVID-19 pandemic and in its immediate aftermath, when services faced considerable strain.

It was important to include a health economic analysis in this feasibility study to inform an economic evaluation if the plan is for the intervention to go to a full definitive trial. It proved possible to collect service use data for the participants with intellectual disabilities and data completeness was good. Missing data were minimal at baseline and missing data at follow-up was largely because it was not possible to follow-up nine participants from Phase 1, due to the COVID-19 pandemic.

BeatIt2 was considered to be an acceptable intervention and therapists and supporters thought that the involvement of individuals with intellectual disabilities in the therapy sessions was a key component of the work. This direct work with individuals who have more severe intellectual disabilities contrasted with the supporters' previous experience of visiting professionals, who adopted a consultation role. The views of supporters in BeatIt2 are consistent with the views expressed by family members in previous research who stressed the importance of professionals working directly with the person with intellectual disabilities (Adams & Jahoda, 2019).

The need to engage the wider group of people supporting the person with intellectual disabilities was viewed as important, to help ensure that the intervention was being implemented. However, therapists and supporters reported that this could prove difficult, given the lack of consistent support some individuals received or due to the poor communication in some support teams. While these may not be factors that therapists can control, careful consideration does need to be given to making connections with the person's wider support team, in addition to the key supporter accompanying the person to sessions.

It is important to acknowledge limitations of the current study. We assessed therapist fidelity to the manual by collecting self-report ratings from therapists themselves. In future studies, it would be important to include a more objective measure of fidelity, such as independent ratings of recordings of the therapy sessions. It should also be noted that the lack of diversity in our participant sample, in terms of race and ethnicity, was a weakness of this study. Therefore, caution should be exercised in generalising from these findings.

The most notable limitation to the study was the suspension caused by the COVID-19 pandemic, which meant that it was impossible to complete the planned RCT. The intervention could not be delivered to most of the participants randomised to the intervention arm, and follow-up data were not collected from participants in the intervention or treatment as usual arms of the RCT.

More positively, it proved possible to recruit to the study even when some COVID-19 restrictions remained in place and researchers could not have face-to-face contact with referrer organisations. It also proved possible to collect data remotely; an approach which could be taken in future studies. Overall, the research findings suggest that future RCT evaluations of BeatIt2 may be feasible and are warranted.

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CONFLICT OF INTEREST STATEMENT

The authors declare there is no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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